identified in §331.11(k)(1), the labeling must continue to bear the first part of the general warning in §330.1(g) of this chapter, which states, ''Keep this and all drugs out of the reach of children.''

(g) [Reserved]

(h) The word ''doctor'' may be substituted for the word ''physician'' in any of the labeling statements in this section.

[39 FR 19874, June 4, 1974, as amended at 47 FR 38484, Aug. 31, 1982; 51 FR 16266, May 1, 1986; 51 FR 27763, Aug. 1, 1986; 52 FR 7830, Mar. 13, 1987; 55 FR 11581, Mar. 29, 1990; 58 FR 45208, Aug. 26, 1993; 59 FR 60556, Nov. 25, 1994; 61 FR 17806, Apr. 22, 1996]

EFFECTIVE DATE NOTE: At 61 FR 17806, Apr. 22, 1996, §331.30 was amended by removing paragraph (c)(5) and redesignating paragraphs (c)(6) and (7) as (c)(5) and (6), and removing paragraph (f) and redesignating paragraph (g) as paragraph (f), effective Apr. 22, 1997. For the convenience of the user, the superseded text is set forth as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(c) * * *

(5) For products containing more than 5 mEq. sodium in the maximum recommended daily dose: ''Do not use this product except under the advice and supervision of a physician if you are on a sodium restricted diet.''

* * * * *

(f) *Statement of sodium containing ingredients.* The labeling of the product contains the sodium content per dosage unit (e.g., tablet, teaspoonful) if it is 0.2 mEq. (5 mg.) or higher.

§ 331.80 Professional labeling.

(a) The labeling of the product provided to health professionals (but not to the general public):

(1) Shall contain the neutralizing capacity of the product as calculated using the procedure set forth in United States Pharmacopeia 23/National Formulary 18 expressed in terms of the dosage recommended per minimum time interval or, if the labeling recommends more than one dosage, in terms of the minimum dosage recommended per minimum time interval.

(2) May contain an indication for the symptomatic relief of hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic esophagitis, gastric hyperacidity, and hiatal hernia.

(3) *For products containing basic aluminum carbonate gel identified in §331.11(a)(1)—Indication.* ''For the treatment, control, or management of hyperphosphatemia, or for use with a low phosphate diet to prevent formation of phosphate urinary stones, through the reduction of phosphates in the serum and urine.''

(4) *For products containing aluminum identified in §331.11(a)—Warnings.* (i) Prolonged use of aluminum-containing antacids in patients with renal failure may result in or worsen dialysis osteomalacia. Elevated tissue aluminum levels contribute to the development of the dialysis encephalopathy and osteomalacia syndromes. Small amounts of aluminum are absorbed from the gastrointestinal tract and renal excretion of aluminum is impaired in renal failure. Aluminum is not well removed by dialysis because it is bound to albumin and transferrin, which do not cross dialysis membranes. As a result, aluminum is deposited in bone, and dialysis osteomalacia may develop when large amounts of aluminum are ingested orally by patients with impaired renal function.

(ii) Aluminum forms insoluble complexes with phosphate in the gastrointestinal tract, thus decreasing phosphate absorption. Prolonged use of aluminum-containing antacids by normophosphatemic patients may result in hypophosphatemia if phosphate intake is not adequate. In its more severe forms, hypophosphatemia can lead to anorexia, malaise, muscle weakness, and osteomalacia.

(b) Professional labeling for an antacid-antiflatulent combination may contain the information allowed for health professionals for antacids and antiflatulents.

[39 FR 19874, June 4, 1974. Redesignated and amended at 55 FR 19859, May 11, 1990]

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.
332.1 Scope.